Title:

Prevention of Postpartum Hemorrhage with Intravenous Tranexamic Acid (PPHIT)

Background:

Hemorrhage remains the leading cause of maternal mortality worldwide. In 2014, in a systematic analysis of the causes of maternal death, the WHO noted that even in the face of interventions developed to actively manage the third stage of labor, 27.1% of maternal deaths were directly attributable to excessive blood loss.¹

Risk factors for postpartum hemorrhage (PPH) have been identified, but the majority of cases occur in low risk women. As such, the routine use of Pitocin or oxytocin in the third stage of labor is recommended in all women, and has been well documented to reduce the risk of excessive blood loss. Uterotonics such as methylergonovine, 15-methyl prostaglandin $F_{2\alpha}$ and misoprostol have shown to be particularly useful adjuncts as decreased uterine tone is the most common etiology of blood loss. More recently, tranexamic acid (TXA) has been shown to be efficacious in the prevention of postpartum hemorrhage in certain cohorts. As

Tranexamic acid exerts its effect through the binding of plasmin and subsequent inhibition of fibrin degradation. It is regarded as pregnancy category B by the Food and Drug Administration (FDA). In 2015, a meta-analysis of 11 randomized controlled trials (RCTs) evaluated the efficacy of TXA on operative blood loss when given prior to cesarean delivery. Women who received TXA had lower rates of hemorrhage, as well as, significantly less need for blood transfusion. A similarly designed meta-analysis (9 RCTs) that same year done by Simonazzi et al reached the same conclusions. This study also noted that the use of uterotonics was significantly reduced in the TXA group.

Other reviews however, do not echo these sentiments, stating that given the size and large range in the design of the studies that the data is insufficient to allow for the recommendation of widespread use of TXA. These reviews included in their analysis the use of TXA in response to PPH. ^{3,4} A larger systematic analysis was then carried out on trials evaluating the prophylactic use of TXA in cesarean deliveries and in response to hemorrhage in vaginal deliveries. A meta-analysis was planned, but not carried out, as the authors found the 26 trials to be small, of poor quality, and with flawed design. They concluded that because of this, there was no reliable evidence that TXA prevents PPH. ⁷

In regards to safety of TXA, because it is an antifibrinolytic, there was concern for venous thromboembolic (VTE) events. None of the before mentioned studies noted any significant differences in VTEs in those treated with TXA compared to controls. Trauma literature supports the safety of TXA both in patients undergoing elective surgery, as well as in emergent trauma patients. The CRASH-2 Trial found that early administration of TXA decreases mortality without increasing the risk for VTE. 8

Current recommendations from the WHO state that TXA should be utilized when first line treatments fail, but further trials on the topic are needed before stronger recommendations can be made. Since the release of that statement, the WOMAN trial results have been published. The investigators evaluated the utility of TXA in treating excessive bleeding status post vaginal and cesarean delivery and found a reduction in mortality secondary to hemorrhage, without an increase in adverse events (to include VTE). On the topic are needed before stronger recommendations can be made. Since the release of that statement, the WOMAN trial results have been published. The investigators evaluated the utility of TXA in treating excessive bleeding status post vaginal and cesarean delivery and found a reduction in mortality secondary to hemorrhage, without an increase in adverse events (to include VTE).

References

- 1. Say L, et al. Global Causes of Maternal Death: A WHO Systematic Analysis. Lancet Global Health. 2014;2(6): e323-e333.
- 2. Zelop, CM. Postparutm Hemorrhage. Becoming More Evidence-Based. Obstet Gynecol 2011; 117; 3-5.
- 3. Sentilhes L, Lasocki S, Ducloy-Bouthors AS, Deruelle P, Dreyfus M, Perrotin F, Goffinet F, Deneux-Tharaux C. Tranexamic acid for the prevention and treatment of postpartum haemorrhage. Br J Anaesth. 2015 Apr;114(4):576-87.
- 4. Novikova N, Hofmeyr GJ, Cluver C. Tranexamic acid for preventing postpartum haemorrhage. Cochrane Database Syst Rev. 2015 Jun 16;(6):CD007872.
- 5. Wang HY, Hong SK, Duan Y, Yin HM. Tranexamic acid and blood loss during and after cesarean section: a meta-analysis. J Perinatol. 2015 Oct;35(10):818-25.
- Simonazzi G, Bisulli M, Saccone G, Moro E, Marshall A, Berghella V. Tranexamic acid for preventing postpartum blood loss after cesarean delivery: a systematic review and meta-analysis of randomized controlled trials. Acta Obstet Gynecol Scand. 2016 Jan;95(1):28-37
- 7. Ker K, Shakur H, Roberts I. Does tranexamic acid prevent postpartum haemorrhage? A systematic review of randomised controlled trials. BJOG. 2016 Oct;123(11):1745-52

- 8. CRASH-2 trial collaborators. Effects of tranexamic acid on death, vascular occlusive events, and blood transfusion in trauma patients with significant haemorrhage (CRASH-2): a randomised, placebo-controlled trial. Lancet. 2010 Jul 3;376(9734):23-32
- 9. WHO Recommendations for the Prevention and Treatment of Postpartum Haemorrhage. Geneva: World Health Organization; 2012.
- 10. WOMAN Trial Collaborators. Effect of early tranexamic acid administration on mortality, hysterectomy, and other morbidities in women with post-partum haemorrhage (WOMAN): an international, randomised, double-blind, placebocontrolled trial. Lancet. 2017 Apr 26.

Research Design:

a. General Approach: Prospective Cohort study

b. Description: Phase 4c. Methods: One Armd. Statistical Analysis:

- SPSS software will be used for our statistical analysis. Normal distribution will be assumed given the intended number of patients for analysis. Categorical variables will be analyzed using the Chisquare test. The t-test will be utilized for the comparison of continuous interval data.
- -Using postpartum hemorrhage rate of 2.86% (institutional data), and a desired impact of reducing the hemorrhage rates by 50% after implementation of the new protocol, then 890 subjects would need to be recruited to answer the question.
 - e. Safety Analysis Plan:
 - Data collection for each participant will occur in real time during pre and post delivery times, therefore safety monitoring of the patient and data will be simultaneous.
 - A Research monitor has been appointed to oversee the safe and ethical conduct of the study. Additionally, the Research Monitor will provide review and comment on any adverse events. The Research Monitor is not a member of the investigative team. The role of the Research Monitor is as follows:
 - 1. monitor the consent process to ensure an absence of coercion
 - 2. monitor data collection/clinical outcome
 - 3. review all adverse event reports with comments from the PI and forward to the IRB with his/her own comments. Adverse events must be received by the IRB within 5 business days of occurrence or reporting (within 24 hours for serious adverse events)
 - 4. ensure the inclusion/exclusion criteria are followed
 - 5. review data security measures
 - Any emerging safety concerns to include any adverse event rate higher than this institution's historical average will result in a halt to the study.

Subject Population:

Pregnant women presenting for delivery at NMCSD

a. Exclusion/Inclusion criteria:

Exclusion:

- a. Age less than 18 years
- b. Planned cesarean hysterectomy
- c. Current anticoagulant use
- d. Subarachnoid hemorrhage
- e. Any active/current intravascular clotting (i.e. venous thromboembolic events)
- f. Patients with a hypersensitivity to TXA or any of the ingredients

- g. History of venous or arterial thrombotic events because use of tranexamic acid is a risk factor for thromboembolism.
- h. Conditions that predispose patients to thromboembolic events (e.g. thrombophilias, autoimmune diseases such as lupus, active cancer, congestive heart failure) because of increased risk of thrombosis
- Patients taking factor IX complex concentrates or anti-inhibitor coagulant concentrates (e.g. FEIBA NF)
- j. Seizure disorder because the use of tranexamic acid has been associated with postoperative seizures
- k. Patients with a baseline creatinine 1.2 or higher, history of renal insufficiency, or renal disease because of the risk of toxicity in patients with preexisting disease.
- I. Patients with frank hematuria because ureteral obstruction due to clot formation has been reported in patients with upper urinary tract bleeding who were treated with tranexamic acid
- m. History of retinal disease as cases of central retinal artery and vein obstruction have been reported in patients treated with tranexamic acid
- n. Patients with acquired defective color vision
- o. Patients with retinal diseases; cases of central retinal artery and central retinal vein obstruction have been reported in patients treated with intravenous tranexamic acid.

Inclusion:

-Pregnant women 18-54 years old delivering at Navy Medical Center San Diego (NMCSD)

Recruitment Process:

Patients will be identified in the antenatal clinics of Naval Medical Center San Diego. All patients that meet the inclusion criteria will be offered inclusion in the study.

All English speaking women who are eligible to receive care at NMCSD and presenting to NMCSD's Labor and Delivery Unit, who are at least 18 years old, not older than 54, and who are scheduled to deliver at NMCSD, will be given verbal and/or a written information sheet about the study and a description of what the study entails. OBGYN staff providers and residents will also be given an information sheet about the study. Opportunities for potential participant recruitment include:

NMCSD Prenatal Registration NMCSD Gestational Diabetes education classes NMCSD Labor and Delivery tour of the unit

Subject eligibility and screening will take place prior to offering potential subjects the opportunity to participate in the study. An eligibility and screening tool will be used as part of the recruitment process.

Consent Process:

Informed consent will be obtained by members of the research team at any point during the subjects routine prenatal care visits.

Consent will only be obtained during a face-to-face communication in a confidential setting.

A member of the research team will provide a verbal and/or written information sheet giving a complete description of the rationale, goals, and requirements of the study. Participants will also be told of the volunteer nature of the study, and that they may cancel their participation in the study at any time, following the process outlined in the consent form.

The PI, AIs, or the research nurse will be available during the recruitment and enrollment phase of the trial. The PI/AI is available throughout the course of this trial. After reading the consent, having all questions answered to their satisfaction, and acknowledging understanding of what is involved in the trial, participants will be asked to sign the consent, along with the research team member obtaining the consent. A copy of the participant's signed consent will be given to them for their personal records.

All consents will include the participant's signature on the IRB-approved consent form. The participant will be given a copy of their signed consent form.

The original signed consent will be kept by the Clinical Research Nurse Coordinator in a locked cabinet in the office of the Clinical Research Nurse Coordinator.

Participants will be informed that they have the right to withdraw from this study at any time. If they decide to stop taking part in this study, they will be asked to tell the principle investigator as soon as possible.

Subject participation may be stopped without participant consent if remaining in the study might be dangerous or harmful in the investigator's opinion. It may also be stopped without participant consent if the military mission requires it, or if the participant loses the right to receive medical care at a military hospital.

Study Procedures:

- 1. Recruitment/Enrollment
 - 1. Identify subjects who meet inclusion criteria at prenatal registration, L&D tours, GDM classes, and on L&D
 - 2. Obtain written consent from potential participants after participant has had time to read, understand and comprehend
 - 3. "TXA Study Participant" to be added to problem list on hard chart, AHLTA template and ESSENTRIS intake
- 2. Implementation on L&D
 - 1. Re-identify patients on admission
 - 2. For patients that present for delivery at a gestational age less than 34 weeks, it will be recommended that they discard their breast milk until 24 hours after their last TXA administration.
 - 3. Order TXA for patient in ESSENTRIS
 - 4. RN to pull TXA from Pyxis and put in patient's room
 - 5. TXA per protocol (see supplement A)
 - 6. The use of additional uterotonics or single additional dose of TXA is at the discretion of the delivering provider
 - 7. For patient monitoring protocol please see Supplement B.
 - 8. All neonates are monitored for a minimum of 24 hours either by the NICU or the Newborn Nursery. Vitals are taken every four hours. Weights and bilirubin levels are obtained daily. Daily physical exams are performed.
- 3. Data collection
 - 1. Participants will be assigned an individualized subject number upon their enrollment to the study.
 - 2. Participants will be followed from their enrollment into the study until six weeks postpartum.
 - 3. An Excel spreadsheet will be used to collect the variables as listed above.
 - 4. Once the variable collection is complete, the information will become de-identified.

5. Chart review will be performed to estimate institutional rates of the secondary outcomes in the 12 months preceding the initiation of the protocol.

4. Data Analysis

- 1. SPSS software will be used for our statistical analysis. Normal distribution will be assumed given the intended number of patients for analysis. Categorical variables will be analyzed using the Chisquare test. The t-test will be utilized for the comparison of continuous interval data.
- 2. Using a postpartum hemorrhage rate of 2.86% (institutional data), and a desired impact of reducing the hemorrhage rates by 50% after implementation of the new protocol, then 890 subjects would need to be recruited to answer the question.
- 3. The secondary outcomes will also be tested against institutional rates. Institutional rates will be estimated by record sampling done at the time of data collection.

Experimental Procedures:

See supplement A

Research materials collected:

Variables to be collected:

Age, race/ethnicity, DoD status, BMI, gestational age, # of fetuses, gravidity, parity, admission diagnoses, admission estimated fetal weight, intrapartum diagnoses, postpartum diagnoses, misoprostol use, oxytocin use, mechanical dilation, duration of labor, magnesium sulfate use, planned mode of delivery, mode of delivery, birth weight, indication for operative delivery, neonatal outcomes, maternal outcomes, admission to the intensive care unit, uterotonic use, mechanical tamponade, blood product transfusion, estimated blood loss, qualitative blood loss, cumulative blood loss, laboratory results, post-delivery laboratory results

Confounding variables:

Management of the 3rd stage of labor

Source of the data:

Outpatient records (AHLTA), Inpatient records (Essentris). As providers, the investigators have access to these systems as a standard of care for patients receiving care from investigator-providers.

Paper records created in the Labor and Delivery department during the course of a delivery.

The data collected will be measured against the historic PPH rates of NMCSD over a period of time to be determined.

Protection of Privacy:

Each participant will be given a unique study number. A master list with only the minimal Personal Identifiable Information (PII) needed for follow up and their study number will be kept in the PI's office on a CAC PIN protected computer in the PI's locked office. The master list will be used to track the results of the study participant's data collection.

An Excel spread sheet will be used to collect this information using only the participants unique study number and stored electronically on a CAC PIN protected computer in the PI's locked office.

All data and PII will be destroyed (shred or deleted) at the conclusion of this project.

Risks:

Within this study, the use of protected health information (PHI) involves no more than a minimal risk to the privacy of individuals as there is a clear plan to protect the identifiers from improper use and disclosure. All identifiers will remain in the protected medical record and any identifier extracted will be destroyed at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by approval of the IRB.

We do not anticipate any risk to subjects participating in this study other than those encountered in routine labor and delivery experiences. TXA is being used in the hopes of reducing the amount of bleeding experienced in postpartum hemorrhage events. It will not eliminate all bleeding or need for a transfusion.

Risk/Side effects of TXA:

Contraindications

- -- Patients with subarachnoid hemorrhage. Anecdotal experience indicates that cerebral edema and cerebral infarction may be caused by TXA in such patients
- -- Patients with active intravascular clotting (e.g. venous thromboembolic events)
- -- Patients with hypersensitivity to TXA or any of the ingredients

Precautions

- -- The dose of TXA should be reduced in patients with renal insufficiency because of the risk of accumulation
- -- Patients with a previous history of thromboembolic disease may be at increased risk for venous or arterial thrombosis. More specifically, patients with DVT within one year, a hypercoagulable genetic disorder, a history of previous stroke, significant coronary artery disease, cardiac stents requiring ongoing clopidogrel (Plavix) treatment, or unstable angina are likely not appropriate candidates for TXA

Adverse Reactions

- -- Gastrointestinal disturbances (nausea, vomiting, diarrhea) may occur but disappear when the dosage is reduced
- -- Allergic dermatitis, giddiness, and hypotension have been reported occasionally
- -- Hypotension has been observed when intravenous injection is too rapid
- -- Rare events from worldwide post marketing reports have included thromboembolic events (e.g., deep vein thrombosis, pulmonary embolism, cerebral thrombosis, acute renal cortical necrosis, and central retinal artery and vein obstruction), convulsion, chromatopsia, and visual impairment

Radiation/Laser Exposure: None

Justification/Minimization of Risks:

All identifiers will remain in the protected medical record. Any PHI extracted as a result of this study will be destroyed at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. Protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by approval of the IRB.

The current Maternal Child Executive Committee Policy on Tranexamic Acid (TXA) Administration will be followed to minimize any risks of harm to subjects.

Benefits:

Potential benefits of the research to the subject include a reduction in blood loss from delivery, decreased need for uterotonic medications, decreased need for blood transfusion, and less morbidity as a result of symptomatic anemia, resulting in increased satisfaction with the postpartum experience and increased maternal-neonate interactions.

Potential benefits of the research to the community/society included less overall maternal morbidity/mortality as well as a decreased demand on limited resources (i.e. blood products, uterotonic medications, time of additional healthcare providers, etc).

Requirements for Research Monitor:

Research Monitor Responsibilities:

Serves as a medical monitor, reviewing AEs as they are discovered to determine if the events suggest a trend toward increased risk to subjects that would require additional safeguards, subject notifications, or an invoking of stopping rules.

To satisfy these two areas of responsibility, the research monitor may discuss the research protocol with the investigators, interview study subjects, and consult with others outside of the project about the research. In the event a problem is identified, they have authority to stop a research protocol in progress, remove individual subjects from a study, and take whatever steps are necessary to protect the safety and well-being of subjects until the IRB can assess the monitor's report.

Research monitors are required to promptly report their medical monitoring and oversight monitoring observations and findings to the IRB or other designated official.

Data Collection Sheets

See attached Excel spreadsheet.

Objectives:

The obstetrics literature to date focuses on TXA use prior to non-emergent cesarean delivery or in response to hemorrhage. Data is lacking in the area of prophylactic use prior to vaginal delivery. The aim of this study will be to assess the ability of TXA to prevent postpartum hemorrhage.

Primary Outcome:

To assess the efficacy of TXA in reducing the incidence of postpartum hemorrhage when given prophylactically prior to all deliveries.

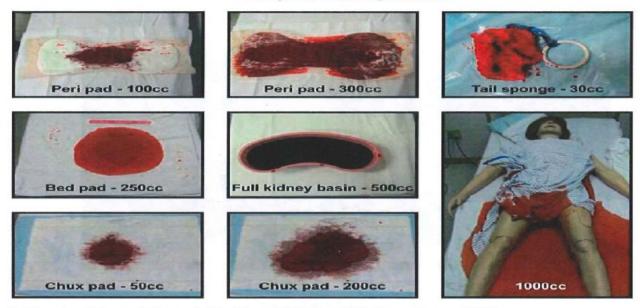
The American Congress of Obstetricians and Gynecologists published 'ReVitalize' in 2014 that defined postpartum hemorrhage as blood loss of >=1000cc or blood loss accompanied by sign/symptoms of hypovolemia to include blood transfusion within 24 hours following the birth process (includes intrapartum loss).

For the purposes of this study, postpartum hemorrhage will be defined as a blood loss of >=1000cc in addition to all patients requiring blood transfusion (even if blood loss is less than 1000cc).

Secondary outcomes:

Estimated blood loss (EBL) – measured in cubic centimeters. EBL will be decided upon by the delivery provider. All delivering providers at this institution have received formal instruction on estimation of blood loss and a visual aid is available at every bedside and in the operating room (see below).

Appendix L Examples of Estimating Blood Loss



Zuckerwise. Estimated Obstetric Blood Loss With Visual Aid. Obstet Gynecol 2014.

Delivering providers will also adhere to NAVMEDWESTINST 6320.20, which specifies that once an EBL reaches 500cc, the delivering provider will move from an *estimation* of blood loss to utilizing a *quantitative* blood loss (QBL). QBLs are obtained by the weighing of chux pads, drapes, and linens that have been soiled (after first calibrating the scale to remove the original weight of the contaminated product). It also includes the blood that has been collected in the suction canister in the operating room.

In instances when EBL is decided upon at delivery, and ongoing bleeding occurs after the provider has left the room (and is called back), a QBL should be obtained. The QBL should be added to the initial EBL for a *cumulative* blood loss (CBL).

Percent decrease in hematocrit (Hct) – The percent change of the patients' Hct obtained on admission from that obtained after delivery. A post-operative Hct is routinely obtained six hours following a cesarean delivery. A Hct is not routinely obtained for patients having a vaginal delivery unless EBL exceeds 500cc. A post vaginal delivery Hct will not be obtained in patients for the sole purpose of this research study.

Rates of blood transfusion – The number of patients requiring blood transfusion divided by the total number of deliveries.

The types and amounts of products transfused – in patients requiring transfusion, the type of product (i.e, packed red blood cells, whole blood, fresh frozen plasma, platelets, and cryoprecipitate) will be recorded, along with how many of each type they received.

The use of uterotonic agents – in patients requiring uterotonic agents beyond the first bolus of oxytocin (i.e. second bolus of oxytocin, methylergonovine, 15-methyl Prostaglandin $F_{2\alpha}$, misoprostol) will be recorded, along with how many doses of each

The need for surgical intervention – the number of patient's that require surgical intervention following a vaginal delivery for the purposes of controlling excessive blood loss divided by the total number of vaginal deliveries

The need for reoperation - the number of patients that require return to the operating room following a cesarean delivery for the purposes of controlling excessive blood loss divided by the total number of cesarean deliveries

Rates of hysterectomy – the number of patients requiring hysterectomy divided by the total number of deliveries

Admission to the Intensive Care Unit (ICU) - the number of patients requiring admission to the intensive care unit secondary to excessive blood loss divided by the total number of deliveries

Neonatal outcomes – incidence of fetal anemia, infection, hyperbilirubinemia, neurologic outcomes, and neonatal intensive unit admissions

Maternal mortality – incidence of mortality

Additionally, postpartum hemorrhage risk assessment will be utilized to stratify patients with regard to primary and secondary outcomes.

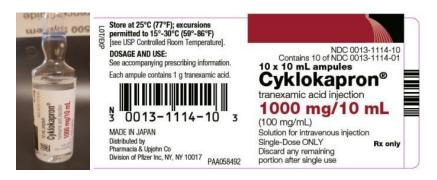
- Patients will be risk stratified to one of three risk categories depending on admission and intrapartum risk factors
 - High Risk Factors:
 - Placenta previa/ low lying placenta
 - Suspected accreta or percreta
 - Platelet count <70,000
 - Active bleeding
 - Known coagulopathy
 - Two or more medium risk factors
 - Medium Risk Factors:
 - Prior cesarean delivery, uterine surgery, or multiple laparotomies
 - Multiple gestation
 - > 4 prior births
 - Prior obstetric hemorrhage
 - Large myomas
 - EFW >4000
 - BMI > 40
 - Hct < 30%
 - Chorioamnionitis
 - >24 hours on Oxytocin
 - Magnesium sulfate
 - Low Risk: all patients not falling in the medium or high risk categories

Importance to Navy Medicine:

Beyond the potential impact that this study has in the reduction of maternal morbidity and mortality, it can also allow for perspective into resource management. Some of the Navy Military Treatment Facilities (MTFs) have limited blood bank stock, and massive hemorrhages requiring ongoing transfusion of products can quickly deplete the entirety of the supply. If we can find a solution that will reduce the number of instances where transfusion is necessary we can help to preserve limited resources. Likewise, this preventive measure will also have the potential to (cost) reduce the need for additional uterotonics, personnel, supplies and ICU beds.

There will be no collaboration with outside institutions.

Supplement A: TXA Protocol Administration (Modified from the NMCSD Maternal Child Executive Committee's Policy)



- 1. TXA comes in a 1000 mg/10 mL vial. Nursing staff will pull this from the Pyxis at the same time they bring Oxytocin into the L&D room.
- 2. Add 1000 mg (or 1 vial) of 1000 mg/10 mL to 100 mL normal saline (100 mg/mL)
 - a. Bolus: 1 gram IV over 10 minutes
 - i. Set infusion pump rate to 600 mL/hr
- 3. Begin the TXA infusion directly following umbilical cord clamping for the intent of preventing postpartum hemorrhage.
 - a. The TXA may be run as a secondary line (i.e. is compatible with pitocin) per CDR Ojo, Chairman of the Pharmacy Department
- 4. TXA should be administered in a separate IV line from blood products.
- 5. Two-person verification is required (this can be a second nurse or can be the physician or certified nurse midwife that is attending the delivery)
- 6. A single additional dose of TXA (1 gram IV over 10 minutes) can be repeated after 30 minutes if bleeding continues or if bleeding stops and then re-starts within 24 hours of the first dose (for a maximum dose of 2g in 24 hours). This additional dose is considered a treatment dose. This additional dose is not required by the study design, which is to assess TXA in the *prevention* of hemorrhage.

Supplement B: Patient Monitoring following delivery

- 1. After delivery patients will be observed on the Labor and Delivery floor for a minimum of one hour. Thereafter they will be transferred to the postpartum ward where they will be observed for a minimum of 24 hours.
- 2. The following physical assessments will be completed every 15 minutes x 1 hour, then every 30 min x 2 hours, then every 4 hours until discharge.
 - A. Vital signs: BP and pulse as above. Temperature Q1 hour (after 2 normal values will space to Q4 hours).
 - B. Fundal assessment: Placement and tone
 - C. Lochia assessment: Color, with or without clots, amount
 - D. Perineum assessment: Intactness (approximation of tissues/wound/lacerations), hematomas, swelling
 - E. Bladder assessment: Distention, voiding (noting/documentation of most recent void/amount, spontaneous/catheterization).
 - F. Any symptoms that the patient reports.
- 3. The nursing staff will immediately report any findings that are not within normal limits to the delivering provider or on-call provider:
 - A. BP systolic > 160 or < 100
 - B. BP diastolic > 90 or <50
 - C. Pulse > 100
 - D. Nausea, dizziness or SOB
 - E. Moderate to copious lochia
 - F. Increased swelling or pain in vagina or perineal/rectal area
 - G. Distended bladder not relieved by catheterization or patient voiding
 - H. Fundus displaced or above umbilicus (if differs from initial normal placement of uterus), unrelieved with empty bladder.

4. Documentation

- A. All assessments are documented in Essentris. See below for notes needed:
- B. Complete intake and output flow sheet
- C. Complete Medication flow sheet
- D. Complete the following computerized nursing notes:
- E. Live Vaginal Delivery:
 - 1. OB MultiD Delivery Summary
- F. Live C/Section:
 - 1. OB MultiD Delivery Summary
 - 2. INTRAOP REPORT-OB
 - 3. SURGICAL/PROCEDURAL CHECKLIST
 - 4. Pre-Op Checklist (unless emergent C/S)

- G. OB Nurse Teach and Discharge Plan
- H. OB Nurse Transfer report*
- I. 24 Hour Nursing Narrative
- J. Postpartum Progress Note
- K. OB MuliD Discharge Summary